

**REMARKS**

**Rejections**

Claims 35-39 are pending in the present application. These claims stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Cleary, *et al.* (Cell, 1986, Vol. 44, pp97-106) ("Cleary") in view of Levy, *et al.*, Journal of Experimental Medicine, 1988, Vol 168 pp475-489 ("Levy") and Embleton, *et al.*, Nucle. Acids. Res., 1992, Vol 20, pp3831-3837) ("Embleton"). For reasons already of record and incorporated here, Applicant respectfully disagrees.

The Examiner now interprets the claims as being used to excrete a multivalent composition, and asserts that the combination of Cleary with Levy and Embleton, if one were to use a multitude of different clones produced according to Embleton, could be used to produce an excreted multivalent composition similar to that produced by the method of the instant claims. (Office Action page 3).

Applicant respectfully points out that the instant claims are to a method of producing a multivalent composition. With respect to the use of a multitude of the clones of Embleton, as suggested by the Examiner (page 3), even if this multitude of clones together could excrete the same multivalent composition produced by the instant method (Applicant does not acquiesce that they could), *this is not relevant to the novelty of instantly claimed method*. Applicant maintains that this combination of references does not teach or suggest the claimed method. In fact, the suggestion to use a multitude of the clones of Embleton is directly contrary to the method of the instantly claimed invention, which is directed to the production of a cell that co-expresses the variable region proteins of interest.

**The references fail to teach each and every element of the instant claims.**

Claim 35 recites, among other things, the following elements:

- a. a plurality of V<sub>L</sub> regions that are inserted into a first expression vector;
- b. a plurality of V<sub>H</sub> regions that are inserted into a second expression vector;
- c. that the pluralities of said first and second expression vectors are co-transformed into a T-lymphoid cell, along with an amplification vector having a specific composition;

- d. that the transformed cell is exposed to a particular aqueous solution, so as to identify a particular transformed cell;
- e. that the particular transformed cell identified in (d) has the features of:
  - i. being capable of growth in the aqueous liquid of (d);
  - ii. expressing a mixture of  $V_L$  and  $V_H$  regions that necessarily are derived from at different tumor cells, as indicated by the recited combinations of different idiotypes;  
(i.e., the transformed cell must co-express a mixture of  $V_L$  and  $V_H$  regions derived from different tumor cells).

These same elements are necessarily included in each of dependent claims 36-39. The references cited by the Examiner, whether taken alone or in any combination, do not teach any of elements (a)-(e), listed above.

Prima facie obviousness *requires* a teaching or suggestion of all the limitations of the claims (MPEP § 2143). "All words in a claim must be considered in judging the patentability of that claim against the prior art." MPEP § 2143.03, citing *In re Wilson*, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970) (*emphasis added*).

The references cited by the Examiner fail to teach or suggest each of the elements of the instant claims listed above. Even if combined, these references *do not even hint* at producing a multivalent composition by producing a T-lymphoid cell that has been transformed to co-express the recited mixtures of  $V_L$  and  $V_H$  regions, as recited in the instant claims. As such, the combination of Cleary, Levy, and Embleton fails to establish obviousness of the instant claims, and Applicant respectfully requests that these rejections be removed.

**CONCLUSION**

For the reasons set forth above, it is respectfully submitted that all reasons for rejection have been addressed and that Applicant's claims should be passed to allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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